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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,805	05/10/2001	Henry Yue	PF-0643 USN	9732

22428 7590 09/27/2004

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EXAMINER

HADDAD, MAHER M

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 09/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/831,805

Applicant(s)

YUE ET AL.

Examiner

Maher M. Haddad

Art Unit

1644

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 09 September 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
- ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.Claim(s) objected to: None.Claim(s) rejected: 21 and 32.Claim(s) withdrawn from consideration: 23,25-31 and 34-44.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____.
10. ☐ Other: _____

Continuation of 5. does NOT place the application in condition for allowance because:

Claims 22 and 32 stand rejected under 35 U.S.C. 112, first paragraph because the specification, while being enabling for the polypeptide comprising an amino acid sequence of SEQ ID NO:6 does not reasonably provide enablement for an isolated polypeptide comprising an amino acid sequence that has at least 95% sequence identity with the amino acid sequence of SEQ ID NO: 6 or a composition thereof. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim for the same reasons set forth in the previous Office Action mailed 6/11/04.

Claims 22 and 32 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant is in possession of SEQ ID NO: 6.

Applicant is not in possession of an isolated polypeptide comprising an amino acid sequence that has at least 95% sequence identity with the amino acid sequence of SEQ ID NO: 6 or a composition thereof for the same reasons set forth in the previous Office Action mailed 6/11/04

Applicant's arguments, filed 9/9/04, have been fully considered, but have not been found persuasive.

Applicant argues that a polypeptide that shares "95% sequence identity" with SEQ ID NO: 6 is one that can accommodate no more than 15 different amino acids. Applicant asserts that claim 22 requires the claimed variant to be functional. Applicant concluded that the skilled person would know which residues of SEQ ID NO: 6 would be amenable to modification. Applicant contends that just as there exists degeneracy of the DNA code, there similarly exists amino acid substitutions that can be made to a polypeptide which are conservative in nature, and which do not alter the basic properties of the residue that is replaced.

Again, Applicant has provided little or no guidance beyond the mere presentation of sequence data to enable one of ordinary skill in the art to determine, without undue experimentation, the positions in the protein which are tolerant to change (e.g. such as by amino acid substitutions or deletions), and the nature and extent of changes that can be made in these positions. Due to the large quantity of experimentation necessary to obtain "5% sequence identity" of SEQ ID NO: 6, to generate a large number of derivatives recited in the claims (for at least 95%, $15^{15} = 759,375$ variation), and to determine the specific activity of the variants, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to the same, the complex nature of the invention, the state of the prior art which establishes that biological activity cannot be predicted based on structural similarity and the breadth of the claims which embrace a broad class of structural variants, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.



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